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VIA ECF

Honorable Joan M. Azrack  
United States District Court  
Eastern District of New York  
Long Island Courthouse  
100 Federal Plaza  
Central Islip, NY 11722

**Re: *Franklin v. General Mills, Inc., et al.*, No. 2:21-cv-01781-JMA-AYS  
General Mills' Response to Plaintiffs' Notice of Supplemental Authority**

Dear Judge Azrack:

We write on behalf of Defendants Annie's Homegrown, Inc. and General Mills, Inc. ("General Mills") in response to Plaintiffs' Notice of Supplemental Authority. Dkt. No. 48 (Jan. 17, 2023). Plaintiffs cite a decision from Northern District of Illinois that dealt with the non-disclosure of phthalates, *Stuve v. Kraft Heins Co.*, No. 21-cv-1845-RRP (N.D. Ill.) (Jan. 12, 2023) ("*Stuve* Order"). Although Plaintiffs argue that the *Stuve* Order supports Plaintiffs' November 16 Letter regarding this Court's inquiry as to current FDA regulatory activity, the *Stuve* court did not address the issue of primary jurisdiction in its opinion at all and for that reason Plaintiffs' Letter may be disregarded. Plaintiffs also use their Letter to challenge General Mills' motion to dismiss; if those arguments are considered, they are distinguishable and in other ways the *Stuve* Order supports dismissal.

**First**, as suggested in this Court's September 30, 2022, docket order, ongoing FDA activity regarding phthalates provides a strong basis for entry of a primary jurisdiction-based stay of this case, an issue that was neither briefed nor considered by the court in *Stuve*. *See also In re: Gerber Prods. Heavy Metals Litig.*, 2022 WL 10197651, at \*5 (E.D. Va. Oct. 17, 2022) (dismissing on primary jurisdiction grounds given ongoing FDA regulatory activity regarding trace heavy metals in food supply).

**Second**, as to issues regarding dismissal the *Stuve* Order reasons that plaintiffs there had alleged a viable "failure to disclose" claim as to the "omission" of information on defendant's labels as to the presence of phthalates. But the court in *Stuve* was never presented with, and so did not consider, the FDA's contrary conclusion that it does not "find it appropriate" to impose any labeling requirements as to trace phthalates. *See* 87 Fed. Reg. 31066, 31077 (May 20, 2022) (Dkt No. 44 at 1) (Nov. 16, 2022). In recent administrative action, the FDA deemed the potential

presence of trace phthalates a fact that is not “material” under the Food, Drug & Cosmetic Act (“FDCA”). *Id.* Thus, applying the FDCA’s “material fact” standard in 21 U.S.C. § 321(n), the Agency concluded no such labeling is required. *Id.* at 3. This conclusion rested in part on the FDA’s assessment of the scientific record, which it concluded did not support a conclusion that there is any presently established safety risk associated with the use of phthalates in the food supply. *Id.* at 2. These twin determinations by the Agency—that the potential presence of phthalates in the food supply is not “material” nor does it pose “safety” concerns—are contrary to the *Stuve* Order’s reasoning that an alleged “safe[ty]” risk for phthalates is plausible, or that its presence is “material.” *Compare id.* at 3 with *Stuve* Order at 14-16.

**Third**, the *Stuve* court accepted plaintiffs’ allegations that the level of phthalates present in defendant’s product was more than “an insignificant level,” treating this as a question of fact and rejecting defendant’s preemption argument. *Stuve* Order at 13-14 (citing 21 C.F.R. § 101.100(a)(3)). In doing so, the court likewise considered, as evidence of a fact dispute, the parties’ complicated and diverging mathematical arguments about the specific levels of phthalates present and whether they exceeded certain “tolerable levels.” *Id.* at 9-10. Here, General Mills resorts to no mathematical computation, and simply correctly notes that plaintiffs do not allege the specific amount of phthalates in Annie’s Products. Plaintiffs’ allegation that level of phthalates present is “not insignificant,” Compl. ¶ 51, is thus conclusory. Plaintiffs’ sole allegation on this point is a legal conclusion masquerading as an allegation of fact, simply parroting the regulation without any facts pled as to amount of phthalates purportedly in Annie’s Products. *See* Dkt. No. 37 at 12.

**Fourth**, the *Stuve* Order broadly supports dismissal of Plaintiffs’ affirmative misrepresentation claims. The court in *Stuve* concluded that no “reasonable consumer” would interpret terms like “NO Artificial Flavors,” or “NO Artificial Preservatives” to mean that the products were completely free of trace phthalates. *Stuve* Order at 20-21. As the court explained, “[t]he alleged presence of a negative substance does not prohibit a manufacturer from advertising a product’s positive qualities.” *Id.* The same analysis applies here: No “reasonable consumer” would interpret claims like “Made with Goodness,” “Bunny of Approval,” “Homegrown” and “Certified Organic” to mean “free from trace phthalates.” *See also George v. Starbucks Corp.*, 857 F. App’x 705, 706 (2d Cir. 2021).

Sincerely,



Charles C. Sipos, pro hac vice

CC: All counsel of record via ECF